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09/280,279	03/29/1999	JON M. MILLER	MILLER.P001	5533

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EXAMINER	
SHARAREH, SHAHNAM J	

ART UNIT	PAPER NUMBER
1617	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Application No. 09/280,279	Applicant(s) MILLER, JON M.	
	Examiner Shahnam Sharareh	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 November 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Continued Prosecution Application

1. The request filed on November 28, 2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/280279 is acceptable and a CPA has been established. An action on the CPA follows.

Effective Filing Date

2. A CPA accompanied by amendment (Preliminary) canceling all claims makes the CPA improper and not entitled to a filing date. Accordingly, the effective filing date of the instant application is November 28, 2001, which is the date the request for CPA is filed. MPEP 706.07 (h), IV, see 37 CFR 1.53(d)(2).

However, Applicant is informed that copendency between the current application and the prior application is required for an application to benefit from priority of an earlier nonprovisional parent application. No copendency existed between the current CPA and its parent application; therefore, the instant application is not entitled to the filing date of its parent application. (see MPEP 706.07 (h), IV, XIII B. table at row # 14). Thus, the effective filing date is November 28, 2001.

Specification

3. The amendment filed on November 28, 2001 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. There are numerous newly add material which were not supported by the original disclosure. The entire page 1-18 does not meet the requirement under 35 USC 132. Applicant is informed that newly amended portions must have adequate support in the original

application. None of the above mentioned pages were disclosed in the original disclosure. Applicant is required to cancel the new matter in the reply to this Office Action.

4. Further, the substitute specification filed November 28, 2001 has not been entered because it does not conform to 37 CFR 1.125(b) and (c) because: it improperly incorporates essential subject matter to the disclosure from PDR without sufficient basis in the original application.

Essential material is defined as that which is necessary to (1) describe the claimed invention, (2) provide an enabling disclosure of the claimed invention or (3) describe the best mode under 35 USC 112. In the instant case, the incorporated material describes the claimed invention and further provides an enabling disclosure and the best mode. See MPEP 608.01 (p) (I-II). Specifically, amended pages 1-18 describe the preferred embodiments of the claimed invention and further provide for the methods of practicing the claimed invention. At numerous places the newly added material relies on subject matter not originally presented. For example page 12 introduces Divalproex as a compound that could be used in the instant claims. Accordingly, the incorporated material attempts to add substantial material to the text of the specification and thus is determined to be improper. MPEP 608.01 (p)

Moreover, Applicant has not provided any affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re*

Hawkins, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973). In fact, the original statement in the application merely refers to another publication. This is not proper incorporation required by 35 USC 112 first paragraphs, because it neither describes exact portions or material of the publication to be incorporated, nor does it recite the incorporation of Sayette's publication in its entirety.

Thus, the substitute specification filed November 28, 2001 has not been entered because it does not conform to 37 CFR 1.125(b) and (c) because: it incorporates essential subject matter to the disclosure of the Application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 32-34, 37,39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Olanzapine is referred twice in the Markush language of the claim 32. Clarification is requested.

Claim 37 recites the term "unconventional antipsychotic drugs" which is ambiguous. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claims 33-34, 39 are dependent on canceled claims. Correction is requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 29-34 are rejected under 35 U.S.C. 102(e) as being anticipated by David Ginsburg Primary Psychiatry, PP 17-20, 8(6), 2001.

The pending claims are directed to compositions comprising a psychotropic active drug and an effective amount of a histamine H2-receptor antagonist and methods of use thereof for controlling weight gain caused by said psychotropic drugs.

Ginsburg discloses that in a 16 week double blind study among patients with schizophrenia wherein patients were receiving olanzapine between 5-20 mg/day, those who received nizatidine 150 mg twice daily experienced significant reduction in weight. Accordingly, Ginsburg discloses all limitations of the instant claims and is anticipatory to the scope of the pending claims.

7. Claims 29-39 are rejected under 35 U.S.C. 102(e) as being anticipated by Jane Todd et al, WO 00/74784 ("'784").

'784 discloses the use of a antipsychotic agent and H2 antagonist to treat weight gain associated with antipsychotic agents (see abstract). "784 enumerates various antispychotic agents such as clozapine and quetiapine that can be taken with H2 antagonists such as cimetidine, ranitidine, famotidine and nizatidine (pages 4-6). '784 also disclose various types of combination and compositions effective for such results (see page 8, lines 25-page 9, line 1; pages 28-38). Accordingly, '784 anticipates the limitations of the instant claims

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 29-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenberg US patent 5,897,910 in view of Deutsch et al (CNS Drugs, 1997, 8(4): 276-284).

Rosenberg teaches process of making tablets comprising one or more active ingredients wherein such active ingredients may be selected from antipsychotics such as clozapine or haloperidol (col 6, lines 15-17), mood stabilizing agents such as valporic acid (col 6, line 47) and histamine H2 antagonists such as cimetidine, famotidine, or nizatidine (col 6, lines 1, 13, 32, 40). Rosenberg fails to teach the instant combination of combinations 6 an antipsychotic agent with a H2 antagonist.

Deutsch generically teaches the therapeutic benefits of adding histamine H2 antagonists such as famotidine, as an adjunctive medication to antipsychotic drugs in treating schizophrenic patients (see abstract, pages 282, and under the heading conclusion).

Although Rosenberg fails to specifically disclose the combination of the instant antipsychiatric agents and H2 antagonists, he states that such combination is possible. Further, Deutsch provides motivation to combine such compounds and administer it to the patient suffering from Schizophrenia. Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to make a single dose composition comprising any antipsychotic agent with an H2 antagonist as taught by Rosenberg, because, as shown by Deutsch, the ordinary skill in the art would have had a reasonable expectation of success in observing clinical benefits among patients in need thereof.

Response to Arguments

9. Applicant's arguments filed on Nov 28, 2001, directed to Deutsch reference on page 3 of the preliminary amendment have been fully considered but are not found persuasive, because they are not commensurate with the scope of the pending claims.

Applicant argues that Deutsch combination is directed to conventional antipsychotic drugs. Except claims 31, none of the pending claims are directed to such limitations; therefore, this line of argument is not commensurate with the scope of the claims.

In response to applicant's argument that Deutsch doesn't teach the instant clinical benefit, species and the mood altering drugs, Examiner replies that the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). In the instant case, the combination of instant species is provided in Rosenburg. Deutsch provides adequate expectation of success to employ such combinations in patients suffering from schizophrenia. Further, the genus of H2 antagonists at current time include only 6-7 active agents, wherein all are substantially and clinically recognized as art equivalents. Therefore, it would have been reasonable to one of ordinary skill to expect similar clinical benefits when combining any H2 antagonists with antipsychotic drugs being used for schizophrenia.

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 703-308-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

Shahnam Sharareh, PharmD
Patent Examiner, AU 1617

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August 24, 2003